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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,236	08/03/2001	David A. Adler	98-71D1	9648

7590

02/11/2004

Jennifer K. Johnson, J.D.  
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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/923,236

Applicant(s)

ADLER ET AL.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 12-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 and 19 is/are allowed.
- 6) ☒ Claim(s) 11 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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Applicant's response to restriction requirement filed 12/17/2003 is acknowledged. Applicant elected Group II invention directed to claims 9, 11 and 19-20 without traverse. Claims 1-8, 12-18 are withdrawn as drawn to non-elected invention.

### **DETAILED ACTION**

Claims 9, 11 and 19-20 are under examination on the merits.

#### ***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides comprising the entire amino acid sequence of SEQ ID NO:2 and residues 16-219 of SEQ ID NO:2, does not reasonably provide enablement for isolated polypeptides comprising residues 16-37, 38-126, 127-219 of SEQ ID NO:2.

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The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification does not teach which critical zsig63 polypeptide residues are in charge of assigning antimicrobial activity to the claimed polypeptides. No examples of such polypeptides are provided either. Current state of prior art indicates that a polypeptide of for example, 5000 amino acids in length which merely **comprises** 21, 88 or 92 amino acids of SEQ ID NO:2 is not capable of retaining function of zsig63 polypeptides of this invention.

Therefore, due to lack of sufficient teachings and examples provided in the specification and due to unpredictability of prior art as to structural requirements of polypeptides comprising 21, 88 or 92 amino acids of SEQ ID NO:2 which retain zsig polypeptide activity one of skill in the art has to go through the burden of undue experimentation in order to pre[are the polypeptides as broadly claimed.

Claims 20 is rejected for depending from the rejected base claim 11.

Claims 11 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The polypeptides of claims 9 (see parts a-c) and its dependent claim 20 are directed to a **genera** of polypeptides which have not been adequately described in the specification.

The specification fails to teach the structural requirements of the following genera of polypeptides;

genus comprising residues 16-37 of SEQ ID NO:2,

genus comprising residues 38-126 of SEQ ID NO :2, and

genus comprising residues 127-219 of SEQ ID NO:2.

Applicant is well aware that a polypeptide of for example 5000 amino acids in length which merely comprises 21 residues of SEQ ID NO:2 is not able to retain antimicrobial activities of szig63 polypeptides. Some additional teaching about the critical residues within such claimed genera is required which is currently lacking in the specification.

Applicant merely provided **a single species** namely polypeptides comprising SEQ ID NO:2, for all claimed genera which is insufficient to put one of skill in the art in possession of the attributes and features of all species within each claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Jacobs (WO 99/101466, 1/14/1999). Jacobs teaches and claims an amino acid sequence (see its SEQ ID NO:10) that does comprise residues 16-37 and residues 38-126 of SEQ ID NO:2 of this invention (see the attached sequence alignment), anticipating claim 11. Said polypeptide of Jacobs is capable of binding an antibody raised to a polypeptide comprising residues 16-37 and residues 38-126 of SEQ ID NO:2, wherein the antibody binding to the polypeptide is measured by a biochemical assay, anticipating claim 20.

***Allowable Subject Matter***

**Claims 9 and 19 are allowed.** This is because an isolated polypeptide consisting of residues 1-15, 16-219, 38-126, 127-219, 16-219 and 1-219 of SEQ ID NO:2 is free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed polypeptide. Since the claimed polypeptide is novel and non-obvious, its fusion products, as specifically claimed, are also novel and non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (517)272-0932. The examiner can normally be reached everyday, except for alternate Mondays.

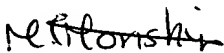
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (517) 272-0928. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**MARYAM MONSHIPOURI, PH.D.**  
**PRIMARY EXAMINER**